Syllabus For

Master of Pharmacy
(M. Pharm)

(Four semester full time programme)

Quality Assurance
(Effective from
June' 2014)

Department of Pharmaceutical Sciences
Saurashtra University
Rajkot - 360 005

Saurashtra University - RAJKOT

Semester & Credit system

For Various Subject specialization of M. Pharm. Programme

M. Pharm. Semester – I

Sr. No.	Subject Code	Type of Subject	Subject	Teaching Scheme		
				Theory Hours/week	Practical Hours/week	**Credits**
1		Interdisciplinary-I	Modern Analytical Technique-I	3	-	**3**
2		Interdisciplinary-II	Practical –I(Modern Analytical Technique-I)	-	6	**3**
3		Core – I	Biological Evaluations and Clinical Research	6	-	**6**
4		Core – II	Practical - II (Biological Evaluations and Clinical Research)	-	12	**6**
5		Core – III	Good Manufacturing and Good Laboratory Practice	4	-	**4**
6		Multidisciplinary - I	Elective – I **1.** Pharmaceutical Preformulation **2.** Pharmaceutical and Industrial Biotechnology **3.** Methods in Biological Evaluation of Drugs	4	-	**4**
					Total Credits	**26**

M. Pharm. Semester – II

Sr. No.	Subject Code	Type of Subject	Subject	Teaching Scheme		
				Theory Hours/week	Practical Hours/week	**Credits**
1		Interdisciplinary-III	Modern Analytical Technique-II	3	-	**3**
2		Interdisciplinary-IV	Practical-III (Modern Analytical Technique-II)	-	6	**3**
3		Core – IV	Modern Pharmaceutical Analysis	6	-	**6**
4		Core – V	Practical - IV (Modern Pharmaceutical Analysis)	-	12	**6**
5		Core – VI	Regulatory Affairs and New Drug Applications	4	-	**4**
6		Multidisciplinary - II	Elective – II 1. NDDS: Multidisciplinary and Regulatory Aspects 2. Analysis of Recombinant Proteins and Diagnostics 3. Quality Improvement Techniques in Drug Manufacturing	4	-	**4**
					Total Credits	**26**

M. Pharm. Semester – III

Sr. No.	Subject Code	Type of Subject	Subject	Teaching Scheme		
				Theory Hours/week	Practical Hours/week	**Credits**
1		Interdisciplinary-V	Research Methodology	4	-	**4**
2		Interdisciplinary-VI	Patent, Design of experiments and Biostatistics	4	-	**4**
3		Core – VII	Validation, product development and stability testing	6	-	**6**
4		Core – VIII	Practical – V (Subject Specialization - V)	-	12	**6**
5		Core – IX	Seminar to Dissertation	4	-	**4**
					Total Credits	**24**

M. Pharm. Semester – IV

Sr. No.	Subject Code	Type of Subject	Subject	Teaching Scheme		
				Theory Hours/week	Practical Hours/week	**Credits**
1		Core- X to XII	Dissertation & Viva-Voice	-	-	**20**
					Total Credits	**20**

Total Credits: 96

M. Pharm. Semester-I
SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Interdisciplinary paper - I
Modern Analytical Techniques-I Theory
(Three hours per week, 3 credits)

OBJECTIVE OF THE COURSE:

To make students familiar with the principles of modern analytical techniques and it's application in pharmacy.

STUDENT LEARNING OUTCOMES/OBJECTIVES:

At the end of the course, the student will be able to understand the fundamental concept of modern analytical techniques, which is important for qualitative as well as quantitative analysis of drug substances and drug product. And also several aspects of the interpretations of the various spectroscopic data.

UNIT-I

UV-VISIBLE SPECTROSCOPY:

Brief review of electromagnetic spectrum and absorption of radiations. The chromophore concept, absorption law and limitations. Theory of electronic spectroscopy, absorption by organic molecules, choice of solvent and solvent effects. Applications of UV-Visible spectroscopy, Woodward –Fischer rules for calculating absorption maximum, interpretation of spectra, multi-component assay, difference spectra and derivative spectra.

INFRARED SPECTROPHOTOMETRY:

Introduction, basic principles, and sampling techniques, interpretation of spectra, applications in Pharmacy. FT-IR, Attenuated Total Reflectance (ATR), near infra red Spectroscopy (NIR) -theory and applications.

UNIT-II

ATOMIC ABSORPTION AND PLASMA EMISSION SPECTROSCOPY:

Principle, instrumentation, interferences and applications in Pharmacy.

REFERENCE STANDARDS

Reference standards source, preparation, characterization, usage, storage and records.

UNIT-III

NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY

Fundamental Principles and Theory, Instrumentation, solvents, chemical shift, and factors affecting chemical shift, spin-spin coupling, coupling constant, and factors influencing the value of coupling constant, spin-spin decoupling, proton exchange reactions, simplification of complex

spectra, FTNMR, 2D -NMR and applications in Pharmacy, interpretation of spectra. C13 NMR-Introduction, Natural abundance, C13 NMR Spectra and its structural applications.

UNIT-IV

MASS SPECTROSCOPY

Basic principles and instrumentation, ion formation and types, fragmentation processes and fragmentation pattern, Chemical ionization mass spectroscopy (CIMS), Field Ionization Mass, Fast atom Bombardment MS (FAB-MS), Matrix assisted laser desorption/ ionization MS (MALDI-MS), Interpretation of spectra and application in pharmacy.

Books Recommended:

1. Instrumental Methods of Analysis - Scoog and West.
2. Spectrometric Identification of Organic Compounds - Silverstein et., al.
3. Instrumental Method of Analysis - Willard Dean & Merrit.
4. Text Book of Inorganic Chemistry — A.I. Vogel.
5. Pharmaceutical Chemistry Vol. I & Vol. II — Becket and Stanlake.
6. Pharmaceutical Chemistry Vol. I & Vol. II — L.G.Chatten.
7. Text Book of Pharmaceutical Analysis - K.A. Connors.
8. Pharmaceutical Analysis — Hiquchi, Bechmman, Hassan.
9. Methods of Drug Analysis — Gearien, Graboski.
10. Text Book of BioPharmaceutic Analysis — Robert Smith and James Stewart.
11. Pharmaceutical Analysis — Modern methods — Part A and B — Munson James. W.
12. Quantitative Analysis of Drugs — Garrot.
13. Quantitative Analysis of Drugs in Pharmaceutical Formulations — P. D. Sethi.
14. IP/BP/USP.
15. Application of Absorption Spectroscopy of Organic Compounds — Dyer.
16. Analytical Profiles of Drug Substances — Florey [Volume 13].
17. Spectroscopy of Organic Compound - P. 5. Kalsi, Wiely Eastern Ltd., New Delhi.
18. Absorption Spectroscopy of Organic Molecules — V. M. Parikh, Addision — Wesley Publishing Company, London.

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – I
Modern Analytical Techniques-I, Interdisciplinary paper - II
Practical-I
(Six hours per week, 3 credits)

1. Use of colorimeter for analysis of Pharmacopoeial compounds and their formulations.
2. Use of Spectrophotometer for analysis for Pharmacopoeial compounds and their formulations.
3. Simultaneous estimation of combination formulations (minimum of 4 experiments)
    a. Vitamins
    b. Oral antidiabetics
    c. NSAIDs
    d. Antimicrobials
    e. Antihistamines
    f. Antihypertensive etc.
4. Effect of pH and solvent on UV Spectrum of certain drugs.
5. Experiments on flame photometry.
6. Use of fluorimeter for analysis of Pharmacopoieal compounds.
7. IR, NMR and Mass Spectroscopy – Interpretation of spectra & Structural elucidation (at least for 4 compounds each).
7. Any other relevant exercises based on theory

M. Pharm. Semester-I
SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – I (Quality Assurance)
Subject of Specialization paper – I (Core Subject-I)
Biological Evaluations and Clinical Research (Theory)
(Six hours per week, 6 credits)

Objective:

To make students familiar with principle of Biological standardization, Sterility testing, Pre-clinical and clinical research, BA- BE studies and Bio-analytical sample preparation and Good clinical practices.

Student Learning Outcome:

At the end of the course, the students will be able to understand the fundamental concept of Pre-clinical and clinical research, Bio-analytical sample preparation, Biological standardization, Sterility testing and BA- BE studies.

Unit-I

a. Biological Standardization**:** General Principles, Scope & limitations of Bioassays. Bioassays of some Official Drugs.
b. Sterility Tests**:** Methodology & Interpretation.
c. Pyrogen - chemistry and properties of bacterial pyrogens and endotoxins. Mechanism of action of pyrogens. Pharmaceutical aspects, pyrogen test of IP compared to that of B & USP. Interpretation of data, Comparison of LAL and other pyrogen tests.
d. Microbiological Limit Tests, Tests for effectiveness of antimicrobial preservatives.

Unit-II

a. Preclinical Drug Evaluation, acute, sub acute and chronic toxicity studies, LD50 & ED50 determination, evaluation of compound for its biological activity, study of special toxicities like teratogenicity and mutagenicity.
b. Clinical Research—
    I. Clinical Research Protocols, objective and protocol design.
    II. Helsinki declaration, US-FDA & ICH guideline for Clinical trials for drugs and dosage forms, reviews and approval of Clinical Study.
    III. Good Clinical Practices.

Unit-III

a. Biological classification system (BCS); its significance on dissolution study and application in dosage form development.
b. Analysis of drugs from biological samples including, selection of biological sample, extraction of drugs by various methods as LLE, SPE and Membrane filtration.

Unit-IV

Bioavailability:- Objectives and consideration in bio-availability studies, Concept of equivalents, Measurements of bio-availability, Determination of the rate of absorption, Bioequivalence and its importance, Regulatory aspects of bio-availability and bioequivalence studies for conventional dosage forms and controlled drug delivery systems.

Unit-V

Pharmacokinetics:- Basic consideration, Pharmacokinetic models, Application of Pharmacokinetics in new drug development and designing of dosage forms and Novel drug delivery systems

Reference Books:

1. Indian Pharmacopoeia (IP'96 , IP 2007)
2. British Pharmacopoeia (BP 2001, BP 2009)
3. U.S. Pharmacopoeia (USP 2002 and latest edition)
4. Bengt Ljunggvist and Berit Davis ―Microbiological Risk Assessment in Pharm. Clean rooms‖. Harwood International Publishing.
5. Richard Prince, ―Microbiology in Pharmaceutical Manufacturing‖. Davis Harwood International Publishing.
6. Akers, ―Parenteral Quality Control: Sterility, Pyrogen, and Package Integrity Testing,‖ 2nd Edition (Marcel Dekker).
7. D. C. Garratt, The Quantitative Analysis of Drugs, CBS Publishers, 2001, New Delhi. Mark C. Rogge and David R Taft, ―Prclinical Drug Development‖, Drugs and Pharm. Sci. Series, Vol. 152, Marcel Dekker Inc., N.Y.
8. Donald Monkhouse, Charles Carney and JimClark, ―Drug Products For Clinical Trials‖. 2nd Ed. v Drugs and Pharm. Sci. Series, Vol. 147, 2nd Ed., Marcel Dekker Inc.,
9. N.Y.Leon Shargel, ―Applied Biopharmaceutics and Pharmacokinetics‖.
10. Welling and Tse.-Pharmacokinetic
11. Gibaldi and Perrier-Pharmacokinetics
12. G. S, Banker & C.T. Rhodes, "Modern Pharmaceutics", Drugs and Pharm. Sci. Series, Vol. 121, 4th Ed., Maracel Dekker Inc., N.Y.
13. Rowland and Tozer-Clinical Pharmacokinetics, concepts and application.
14. Notari.-Biopharmaceutics and Pharmacokinetics-An introduction.
15. John Wagner- Pharmacokinetics for Pharmaceutical scientist.
16. R V Smith, J T Stewart, Textbook of Bio Pharmaceutical Analysis.

M. Pharm. Semester-I
SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – I (Quality Assurance)
Subject of Specialization paper – I (Core Subject-II)
Biological Evaluations and Clinical Research (Practical)
(Twelve hours per week, 6 credits)

PRACTICAL:

1. Oral and practical examination in general course illustrative of theory section
2. Statistical analysis include data acquisition, processing and retrievals
3. Practice in developing of analytical method of drug substances
4. To determine the effect of different factors affecting absorbance maximum wavelength
5. The calibration of lab equipment as well as apparatus.
6. To perform assay of different pharmaceutical formulation as per IP.

M. Pharm. Semester-I
SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – I (Quality Assurance)
Subject of Specialization paper – II (Core Subject-III)
Good Manufacturing and Good Laboratory Practice
(Four hours per week, 4 credits)

Objective:
To make students familiar with the principle of quality Assurance, Good manufacturing Practices and Good Laboratory Practices and its application in pharmaceutical industry.

Student Learning Outcome:
At the end of the course students will be able to understand the fundamental concepts of Quality control and Quality Assurance which is important to maintain quality and safety of pharmaceutical product.

Unit-I **12 Hours**

a. Concepts of Philosophy of Quality assurance, GMP, cGMP, GLP has applied to the pharmaceutical industry
b. WHO certification scheme
c. Development of Monograph
d. Self inspection and Quality audit, loan licensing Audit-concept, Auditing

Unit-II **12 Hours**

Good Manufacturing Practices

a. Organization & Personnel, responsibilities, training, hygiene.
b. Premises: Location, design, Plant Layout, Construction, Maintenance and Sanitation, Environmental control, utilities and services like gas, water, maintenance of sterile areas, and control of contamination.
c. Equipments: Selection, purchase specifications, maintenance, clean in place, sterilize in place, Methods (TP & STP).
d. Raw Materials: Purchase specifications, maintenance of Stores, selection of Vendors, control on raw materials and finished dosage forms.

Unit-III **12 Hours**

a. Manufacture of & control on dosage forms: manufacturing documents, master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities.
b. In Process quality controls on various dosage forms: Sterile and non sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfections, sterilization, membrane filtration etc.

c. Packaging and labelling control, Line clearance, reconciliation of labels, cartons and other packaging materials.

Unit-IV **12 Hours**

a. Quality control Laboratory: Responsibilities. Routine controls instruments, reagents, sampling plans, standard test Procedures, protocols, data generation and storage, quality control documents, retention samples, records, audits of quality control facilities.
b. Finished product release, quality review, quality audits and batch release documents.
c. Warehousing, design, construction, maintenance and sanitation; good warehousing practice, materials and management.
d. Distribution and distribution records, handling of returned goods, recovered materials and reprocessing. Complaints and recalls, evaluation of complaints, recall procedures, related records and documents.
e. Waste disposal, scrap disposal procedures and records.

Unit-V **12 Hours**

a. Good Laboratory Practice
b. Specifications for materials, intermediates and finished product.
c. Testing of packing material

Reference Books:

1. Sidney H. Willig, "Good Manufacturing Practices for Pharmaceuticals", Drugs and Pharm. Sci. Series, Vol. 135, 4th Edition., Marcel Dekker Inc., N.Y
2. S. Weinberg, –Good Laboratory Practice Regulation‖ Drugs and Pharm. Sci. Series, Vol. 124, 3rd Ed., Maracel Dekker Inc., N.Y.
3. Syed Imtiaz Haider , –Pharmaceutical Master Validation Plan, The ultimate guide FDA, GMP and GLP Compliance‖ , St. Lucie Press , 2006
4. Joseph D. Nally, –Good Manufacturing Practice For Pharmaceuticals‖, 6th edition, Informa Healthcare.
5. P. P .Sharma –How to practice GMPs‖, 3rd edition Vandana Publication.
6. P. P. Sharma –How to practice GLP‖ Vandana Publication.
7. John Sharp, –Good Pharmaceutical Manufacturing Practice‖ , CRC Press.
8. David M. Bliesner , – Establishing A CGMP Laboratory Audit System, A practice Guide‖ , A John Wiley & Sons, INC Publication.
9. S. Bolton, "Pharmaceutical Statistics: Practical & Clinical Applications", Drugs and Pharm. Sci. Series, Vol. 109, Marcel Dekker Inc., N.Y.
10. G. S, Banker & C.T. Rhodes, "Modern Pharmaceutics", Drugs and Pharm. Sci. Series, Vol. 121, 4th Ed., Maracel Dekker Inc., N.Y.
11. WHO's –Drug‖ Bulletins.
12. Remingtons ―Pharmaceutical Sciences‖.
13. GMP practices for pharmaceutical-James Swarbrick.

Multidisciplinary/ Elective Subject-I SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – I Multidisciplinary / Elective paper - I

Pharmaceutical Preformulation Theory (Four hours per week, 4 credits)

UNIT – I General Considerations, Spectroscopy and Assay development, dissociation, partitioning and Solubility of Pharmaceutical Solids, pKa, salts, solvents, K , drug design, phase solubility analysis, solubilization, release, dissolution and permeation, chiral drug substances, characterization scheme.

UNIT – II Solid state properties, crystal morphology, melting point and its analysis, microscopy and particle size analysis, laws of crystallography, habit, polymorphism, pseudomorphism, isomorphism, purity, solubility, hygroscopicity, study methods for evaluation of solid state.

UNIT - III Dosage form consideration in preformulation, solid dosage form, solution formulations, emulsion, suspension, freeze dried products, topical, pulmonary, evaluations and its regulatory considerations, stability tastings, order of reaction, antioxidants, chelating agents, impurity, GMP related to bulk drugs and APIs.

UNIT – IV Characterization of Biopharmaceutical drugs and Phytomedicines.

REFERENCES

1. Modern Pharmaceutics by G. Banker.
2. Physical Characterization of Pharmaceutical Solids by H. Brittain.
3. Polymorphism in Pharmaceutical Solids by H. Brittain.
4. Solid State Chemistry of Drugs by S.R. Byrn.
5. Chemical Stability of Pharmaceuticals by K.A. Connors.
6. Pharmaceutical Preformulation and Formulation by M. Gibson.
7. Solubility Behavior of Organic Compounds by D.J.W. Grant and T. Higuchi.
8. Remingtons ―Pharmaceutical Sciences‖ 19th edition.
9. Pharmaceutical Preformulation by J. Wells.
10. Solubility and Solubilization in Aqueous Media by S. Yalkowsky.
11. Pharmaceutics –The Science of Dosage form design‖ by Aulton.
12. Hand book of Preformulation by Sarfaraz K. Niazi.

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – I
Multidisciplinary / Elective paper - I Pharmaceutical and Industrial Biotechnology Theory (Four hours per week, 4 credits)

Unit I

Industrial aspects: Stability studies of biotechnology derived products, Effects of various environmental /processing on stability of the formulation and techniques for stabilization of product against the same regulatory requirement related to stability testing with emphasis on matrixing bracketing techniques, Climatic zones

Unit II

Concept of biotech process validation, Cell lines culture process validation and characterization, Purification process for viral clearance, validation of recovery, Purification, Cleaning, Filtration, Issues of DNA vaccines and plasmid DNA vaccines

Unit III

Analytical methods in protein formulation: concentration, size, purity, surface charge, identity, structure/sepuence, shape, activity.

Unit IV

Industrial application of biotech products: industrial enzymes (examples), immobilization of enzymes, their applications in industry, Immobilized Enzyme engineering, Kinetics of immobilized enzymes, novel methods for enzyme and vaccine production.

READING MATERIAL

1. **Jens T. Cartensen and C. T. Rhodes**, Drug stability principle and practice, 3 ed. Vol. 107, Marcel Dekker
2. **Rodney pealman, Y. John wang,** formulation characterization and stability of protein drugs, (1996)
3. **Eugene J. McNally, Jayne E. Hasted**, protein formulation and delivery 2 Ed. Informahealthcare.

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – I
Multidisciplinary / Elective paper - I Methods in Biological Evaluation of Drugs Theory (Four hours per week, 4 credits)

Unit-1

A. Biological standardization, general principles, Scope and limitation of bio-assay, bioassay of some official drugs.

B. Preclinical drug evaluation of its biological activity, potency and toxicity-Toxicity test in animals including acute, sub-acute and chronic toxicity, ED 50 and LD determination, special toxicity test like teratogenecity and mutagenecity. Various guidelines for toxicity studies. Animal experiments assessing safety of packaging materials.

C. Selected topics in screening of drugs:
a. Recent advances in Transgenic and Knockout animals **b.** Administration of Neuropeptides and Neurohormones by Intracerebroventricular (ICV) route in rats. **c.** Screening models for drug abuse like alcohol addiction, dependence and withdrawal syndrome. **d.** Biostatistics and calculation of doses in experimental pharmacology

Unit -2

A. Pyrogens: Sources, Chemistry and properties of bacterial pyrogens and endotoxins, Official pyrogen tests
B. Microbiological assay of antibiotics and vitamins.
C. Biological evaluation of drugs--Screening and evaluation (including principles of screening , development of models for diseases : In vivo models / In vitro models / cell line study) techniques of the following:

Unit -3

A. Parasympathomimetics, Parasympathetic blocking agents, Sympathomimetics, Sympathetic blocking agents, Ganglion stimulants and blockers, Neuromuscular stimulants and blockers.
B. General and local Anesthetics, Sedatives and Hypnotics, Antiepileptics, Psychopharmacological agents, Analgesics, Anti-inflammatory agents, Anti-Parkinson's drugs, CNS Stimulants.
C. Cardiotonics, Anti-hypertensive drugs, Anti-arrhythmic drugs, Drugs used in Ischemic Heart Diseases, Drugs used in Atherosclerosis.

Unit -4

A. Drugs used in Peptic Ulcer, Respiratory disorders, Hormone and Endocrine disorders. Anti fertility agents and diuretics.
B. Various models for Cataract, glaucoma, inflammatory bowel disease

Books recommended (Latest Edition):

1. Screening methods in pharmacology (vol I & II)–R.A. Turner
2. Drug Discovery and Evaluation in Pharmacology assay: Vogel
3. Design and analysis of animal studies in pharmaceutical development, Chow, Shein, Ching.
4. Evaluation of Drug Activity: Pharmacometrics D.R. Laurence
5. Animal and Clinical pharmacologic Techniques in Drug Evaluation-Nodine and Siegler
6. Pharmacology and Toxicology- Kale S.R.
7. Fundamentals of experimental Pharmacology- Ghosh M.N.
8. Handbook of Experimental Pharmacology- Goyal R.K.
9. Handbook of Experimental Pharmacology- Kulkarni S.K.

M. Pharm. Semester-II
SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – II (Quality Assurance)
Subject of Specialization paper – III (Core Subject-IV)
Modern Pharmaceutical Analysis (Theory)
(Six hours per week, 6 credits)

Unit-I

a. Application of analytical methods to product obtained through genetic engineering, Amino acid sequence analysis, Tryptic mapping, ion exchange amino acid analysis, isoelectric focusing
b. Calibration of various instruments used for drug analysis

Unit-II

a. Dissolution study: Importance, objectives, equipments,
b. Selection of dissolution medium and conditions,
c. Comparison of dissolution profile by similarity and dissimilarity factor
d. In-vivo and In- vitro Co-relation (IVIVC)

Unit-III

a. Analytical aspects of preformulation study
b. Applications of various analytical techniques in preformulation analysis and its Importance
c. Regulatory requirement in pharmaceutical analysis – US-FDA, ICH

Unit-IV

a. In-process quality control tests for Tablets, Capsule, Liquid orals, Ophthalmic applications, Aerosols, Sterile parenterals and Scale up operations including packaging and labelling operations.
b. Analysis of drug from biological fluid
c. Analysis of Cosmetics

Unit-V

a. Compendial testing
b. Automated analysis
c. Compendial methods for evaluation of crude drug and herbal formulation

References Books:

1. Harry G Brittain, Spectroscopy of Pharmaceutical Solids, Drugs and PharmSci.Series,Vol. 160, Taylor and Francis, 2006 N.Y.
2. S. Ahuja, Modern Pharmaceutical Analysis
3. Lena Ohannesian and Anthony J. Streeter, Hand Book of Pharmaceutical Analysis, Pharm Sci. series, Vol. 117, Maarcel Dekker Inc., N.Y
4. Peptide and Protein Drug Analysis, by Reid, (Marcel Dekker).
5. Classification of cosmetics raw materials and adjuncts IS 3958 of Indian Standards Institution (BIS).
6. Cosmetic and toilet goods – methods of sampling IS 3958 of Indian Standards Institution (BIS).
7. Methods of sampling and test for various cosmetics as laid down by Indian Standard Institution (BIS).
8. Indian Pharmacopoeia,Vol. I and Vol. II - 1996.The Controller of Publications; New Delhi, Govt. of India,
9. The International Pharmacopoeia Vol 1,2,3,4, 3rd Edition General methods of analysis and quality specifications for pharmaceutical substances, excipients, dosage forms.
10. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials Vol.1 and Vol.2, WHO, (1999)
11. Basic tests for pharmaceutical substances – WHO (1988)
12. Basic tests for pharmaceutical dosage forms – WHO (1991)
13. Phytochemical Methods by J.B.Haroborne
14. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – II (Quality Assurance)
Subject of Specialization paper – III (Core Subject-V)
Modern Pharmaceutical Analysis (Practical)
(Twelve hours per week, 6 credits)

1. Oral and Practical examination in general course illustrative of theory section.
2. Practice in analysis of solid oral dosage form, Injectable dosage form, Drugs in biological fluids and cosmetics, Packaging material
3. Dissolution studies, Comparison of dissolution profile by similarity and dissimilarity factor and IVIVC
4. Determination of active constituents in crude drugs. Eg. Caffeine from tea powder, curcumin from curcuma longa, quinine from cinchona bark etc.
5. Quality Control tests for some herbal formulations.
6. Quality Control tests for some cosmetics

SAURASHTRA UNIVERSITY M. PHARM.
SYLLABUS Semester – II (Quality Assurance)
Subject of Specialization paper – IV (Core Subject-VI)
Regulatory Affairs and New Drug Applications Theory
(Four hours per week, 4 credits)

Unit I

a. Contract manufacturing
b. Certification and Licensing Procedures
c. Quality Safety and Legislation for Cosmetic and Herbal products
d. Site Master File
e. Drug Master File
f. Material Safety Data Sheet (MSDS) preparation

Unit II

a. Industrial Safety & Health Guide lines for filing in countries like US & EU
b. Drug Regulatory Agencies-Historical perspectives, organization structure activities & responsibilities: India US, EU, Japan, ICH
c. Study of compendia – Evolution, Study of parts of compendia like: Polices, General notice, Monographs, Comparative picture of IP, USP, BP, & EP.

Unit III

a. Drug regulatory and accrediting agencies of world and their guidelines including USFDA, MCA, TGA, MHRA, ANVISA, CTD, WHO, ICH, SUPAC etc.
b. Common Technical Document (CTD)
c. Electronic version of the Common Technical Document (eCTD)

Unit IV

a. Investigational New Drug (IND) application, format & content of IND, general consideration of New Drug Application (NDA) and Abbreviated New Drug Application (ANDA) and specific requirements, content & format of NDA and ANDA

Unit V

a. Legislation to regulate, import, manufacture distribution and sales of drug and cosmetic Act 1940 & rules 1945 with amendments.
b. Regulatory aspects of pharmaceutical and bulk drug manufacture and biotechnology derived product.
c. Aims, objects and salient features of following legislations governing Pharmaceutical Industry-

i. Pollution Control Act
ii. Prevention of Food Adulteration Act 1954
iii. Industrial Development & Regulation Act 1951
iv. Consumer Protection Act

References Books:

1. Drugs and Cosmetics Laws by Krishnan Arora, Professional Book Publishers, New Delhi
2. Mittal B.M., A Textbook of Forensic Pharmacy, 9th Ed., Vallabh Prakashan
3. Deshpande S.W., Drugs and Cosmetic Act.1940.
4. Gnarino Richard A, New Drug Approval Process, 3 rd Ed., Marcel Dekker Inc.
5. P. Warayan, Intellectual Property Laws, Eastern Law House.
6. Drug and Cosmetic Act 1940, Eastern Book company by Vijay Malic, 11th Ed. Patents for Medicine, by N. B. Zareri, Indian Drug Manufacturers Association (IDMA)
7. Ira R. Bery, ‐Introduction to the Pharmaceutical Regulatory Process‖, Drugs and Pharm Sci. Series, Vol. 144, Marcel Dekker Inc., N.Y.
8. The Drugs and Cosmetic Act 1940 – Vijay Malik
9. Indian Pharmacopoeia, Vol. 1-3, 2007.The Indian Pharmacopoeia commission, Gahaziabad, Govt. Of India.
10. The International Pharmacopoeia Vol 1, 2,3,4,5 3rd Editions
11. Pollution Control Act, 1974
12. Prevention of Food Adulteration Act 1954
13. Industrial Development & Regulation Act 1951
14. Consumer Protection Act 1986
15. ‐WHO Expert Committee on specification on Pharmaceutical Preparation‖34th report, Geneva, World Health Organisation, 1996 (WHO Technical Report Series, No. 863
16. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials Vol.1 and Vol.2, WHO, (1999)
17. A.C. Cartwright and Brian Mathews,‖International Pharmaceutical Registration‖ Taylor and Francis Ltd. UK, 2002
18. United State Pharmacopoeia (USP) 32,NF27, 2009
19. Industrial Health and Safety, Dr. A.M. Sarma, Himalaya Publication.

Multidisciplinary/ Elective Subject-II SAURASHTRA UNIVERSITY
M. PHARM. SYLLABUS
Semester – II Multidisciplinary /
Elective paper – II
NDDS: Multidisciplinary and Regulatory Aspectrs Theory
(Four hours per week, 4 credits)

UNIT- I

Introduction and overview of Novel Drug Delivery Systems (NDDSs) - Particulate Drug delivery (Microshpres, Microcapsules, Nanosheres, Nanocapusels, Polymeric beads, etc.) - Vesicular Drug delivery (Liposmes, Ethosomes, Neosomes, etc.) - Insitu gelling systems - Transdermal Drug delivery - Microemulsion, Nanoemulsion, Self emulsifying systems, Nanosuspension,etc. - Targeted Drug delivery - Liquid and Semisolid preparations - Sterile products, Cosmetic products and Aerosolized systems.

UNIT- II

Consideration of various regulations in product development - Organic volatile impurities - Trace impurities - API and product stability - Product registration

UNIT- III

Biotechnoligical Products: - Formulation development aspects for biotechnological products - Delivery aspects for biotechnologically derived products (Recombinat DNA, Recombinat proteins, Gene delivery, Enzymes, Hormones, etc.) - Product stabilization aspects with consideration of ICH QE5 Section. - Regulatory considerations with consideration of global regulatory guidelines.

UNIT- IV

Herbal and naturally derived Products: - Formulation development aspects - Delivery aspects for herbal and naturally derived medicinal products (Herbal extracts, crud extracts, incorporation of product performance enhancers, etc.) - Product stabilization aspects with consideration of ICH guideline. - Regulatory considerations with consideration of global regulatory guidelines.

UNIT- V

Synthetic and Semisynthetic medicines - Formulation development aspects - Delivery aspects for Synthetic and Semisynthetic medicines. - Product stabilization aspects with consideration of ICH guideline. - Regulatory considerations with consideration of global regulatory guidelines.

Books Recommended:

1. Remingtons “Pharmaceutical Sciences” 19th Edition.
2. Pharmaceutics “The Science of Dosage Form Design” by Michael Aulton
3. Pharmaceutical Dispensing by Husa
4. Dispensing Pharmacy by Cooper and Goons
5. Encyclopedia of Pharmaceutical Technology, Volumes: I-VI, 3 rd Edition
6. www.fda.gov/RegulatoryInformation/Guidances
7. Drug stability (Principles and Practices) by Jens Carstensen
8. Stability of drugs and dosage forms by Yoskioka
9. Modern Pharmaceutics by G. S. Banker
10. Biodegradable polymers as drug delivery systems by Cahsin

SAURASHTRA UNIVERSITY
M. PHARM. SYLLABUS
Semester – II
Multidisciplinary / Elective paper – II
Analysis of Recombinant Proteins and Diagnostics Theory (Four hours per week, 4 credits)

A. Analysis: Unit I

- **Total protein assay:** Quantitative amino acids analysis, Folin-Lowry protein assay, BCA assay, UV spectrophotometry etc.
- **Purity:** Protein impurities, contaminants, electrophoretic analysis, HPLC based analysis, DNA content analysis, immunological assays for impurities, combined immunological and electrophoretic methods, host-cell impurities etc.

Unit II ➢ **Test procedures:** ICH guidelines.

➢ **Potency assays:** In-vitro biochemical methods. cell-line derived assays, whole animal assays etc.

B. Diagnostics:

Unit III ➢ Principles, methods and applications: Principles and methods of some clinically used diagnostic immunoassays, e.g., homogeneous immuno assays, fluorescence, chemiluminescence and bioluminescence enzyme immunoassays etc., immunosensors.

UnitIV

- Principles, methods applications: DNA probe based diagnostics, sample preparation, hybridization, separation, detection, PCR-RFLP in paternity and forensic cases, SNP detection MALDI and DHPLC.
- Cancer diagnostics, human retroviral diseases specially AIDS. Role of enzymes in diagnostics.

READING MATERIAL

1. Practical Biochemistry: Principles and Techniques, Fifth Edition – 2005, K. Wilson and J. Walker
2. Experimental Biochemistry, Third Edition – 1999, R. L. Switzer and L. F. Garrity W. H. Freeman and Company
3. US Pharmacopeia Vol. 1-3 National Formulary 25, 2007 (Biotechnological drugs) The USP Convention
4. Indian Pharmacopoeia -2007 Vol. 1-3 (Biotechnology products) The IP Commission, Ghaziabad
5. Related review Articles

SAURASHTRA UNIVERSITY
M. PHARM. SYLLABUS
Semester – II
Multidisciplinary / Elective paper – III
Quality Improvement Techniques in Drug Manufacturing Theory
(Four hours per week, 4 credits)

UNIT- I

International Organization for Standard – ISO, Grading, Documents specified by ISO like control of records, control of manufacturing, preventive maintenance, control of documents, corrective action, Internal audits etc and its relevance with Quality Drug Manufacturing

UNIT- II

Total Quality Management and Process steps of Total Quality Management (TQM) Statistical process control – SPC

UNIT- III

Six Sigma including concept of Defects Per Million Opportunities (DPMO), DMAIC process (Define, Measure, Analyze, Improve, and Control), DMADV process (Define, Measure, Analyze, Design, Verify) and DFSS (Design For Six Sigma)

UNIT- IV

Process and Analytical Technology – PAT Failure Mode Effect Analysis – FMEA

UNIT- V Lean manufacturing Malcolm Baldrige National Quality Award – MBNQA European Foundation for Quality Management (EFQM) excellence model

M. Pharm. Semester-III SAURASHTRA
UNIVERSITY M. PHARM. SYLLABUS Semester – III
Interdisciplinary paper - V
Research Methodology Theory
(Four hours per week, 4 credits)

1. Research-Meaning, purpose, Types, (Educational, Clinical, Experimental, historical descriptive, Basic applied and Patent oriented Research) objective of research

2. Literature survey-Use of Library, books and journals-Medlines-Internet, Patent Search, and reprints of articles as a source for Literature survey.

3. Selecting a problem and preparing Research proposals

4. Methods and tools use in research –
   A. Qualities studies, quantitative studies
   B. Simple data organization descriptive data analysis,
   C. Limitation & sources of Error
   D. Inquiries in form of Questionnaire, etc.,

5. Documentation-
   "How" of documentation
   Techniques of documentation
   Importance of documentation
   Use of computer packages in documentation.

6. The Research Report Paper writing/ thesis writing
   Different parts of the Research paper

A. Title –Title of project with authors name
B. Abstract- Statement of the problem, Background list in brief and purpose and scope.
C. Key Words.
D. Methology-subject, apparatus, instrumentation & procedure.
E. Results- tables, graphs, figures & statistical presentation
F. Discussion support or non support of hypothesis, practical & theoretical Implications
G. Conclusion
H. Acknowledgements.
I. References
J. Errata
K. Importance of Spell check for entire project

L. Uses of footnotes

7. **Presentation** (especially for oral presentation)
   Importance, types different skills, contained, format of model, introduction, Poster, Gestures, eye contact, facial, expressions, stage, fright, volume- pitch, speed, pause & language, Visual aids & seating, Questionnaire

8. Cost analysis of the project – cost incurred on raw materials- Procedure, instrumentations and clinical trials.

9. Sources for procurement research grants – international agencies, Government and private bodies,

10. Industrial-institution interaction- Industrial projects, their, feasibility reports. Interaction with industries

Recommended Books: -

1. Research In Education- John V. Best, John V. Kahn 7th edition
2. Presentation skills - Michael Hallon- Indian Society for Institute education
2. Practical Introduction o copyright.- Gavin Mcfarlane
3. Thesis projects in Science & Engineering – Richard M. Davis.
4. Scientist in legal Systems- Ann labor science
5. Thesis & Assignment – Jonathan Anderson
6. Writing a technical paper- Donald Menzel
7. Effective Business Report Writing –Leland Brown
8. Protection of industrial Property rights- P. Das & Gokul Das
9. Spelling for the millions- Edna Furmess
10. Preparation for publication – King Edward Hospital Fund for London
11. Information Technology – The Hindu speaks
12. Documentation – Genesis & Development 3792.
13. Manual for evaluation of industrial projects-United Nations
14. Manual for the preparation of industrial feasibility studies

SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS

Semester – III

Interdisciplinary paper - VI

Patent, Design of experiments and Biostatistics

(Four hours per week, 4 credits)

UNIT-I

1. Intellectual property, importance and types of intellectual property.
2. Paris conventional, World Trade Organization, WIPO and GATT.
3. US Patent System and European Patent System

UNIT-II

The Indian Patents Act 1970 and Indian patents (Amendments) Act 2005 and issue related to Patents, Importance, parts of patent, type of patent, provisional application, Oppositions, Patent infringement, Patent search engines

UNIT-III

Biostatistics and Various statistical methods i. e.Null hypothesis, t- Test, Regression analysis, ANOVA, Chi-square, etc.

UNIT- IV

Optimization Techniques and its applications in relation to subject specialization
Design of experiments, Factorial designs
Grid search technique, Response surface methodology, contour plots, etc. its application in pharmaceutical sciences.

M. Pharm. Semester-III
SAURASHTRA UNIVERSITY M. PHARM. SYLLABUS
Semester – III (Quality Assurance)
Subject of Specialization paper – V (Core Subject-VII)
Validation, Product development and stability testing
(six hours per week, 6 credits)

Unit-1 **12 hrs**

Introduction to Pharmaceutical Validation:
Definition, scope of Validation, Advantage of Validation, Organization for Validation, Validation Master Plan, Types of process validation, Design Qualification, Installation Qualification, Operational Qualification & Performance Qualification of facilities.

Process Validation
Prospective, concurrent, retrospective & revalidation, Process validation of following formulations

- Tablets
- Capsules
- Ointment/Creams
- Liquid Orals
- Parental

Unit II **12 hrs**

Utilities Validation

- Validation of Pharmaceutical Water System
- Validation of HVAC system

Computer System Validation
Cleaning Validation: Cleaning Techniques, Cleaning of Equipment, Cleaning of Facilities

Unit III **12 hrs**

Analytical Method Validation
General principles of analytical method validation.
Development of new analytical method and its validation
Validation of following analytical Instruments

- HPLC/HPTLC
- Dissolution test apparatus
- U.V./Visible spectrophotometers

Calibration Master plan
Validation of Equipment

Validation of following Equipment/Process

- Dry Powder Mixers
- Fluid Bed and Tray dryers.
- Tablet Compression (Machine)
- Dry Heat Sterilization, Moist heat sterilization, Gaseous sterilization, Radiation sterilization and Membrane filtration

Unit IV **12 hrs**

- Basic concept and objectives of stability study,
- Order of reaction and their application in predicting shelf life and half-life of pharmaceutical formulations,
- Importance of accelerated stability study,
- Effect of various environmental/processing factors (i.e. light, pH, metal etc.,) on stability of the formulation, Regulatory requirement related to stability testing with emphasis on matrixing/bracketing technique, climatic zone, photo stability testing etc.,

Unit V **12 hrs**

- Application of ICH Quality guideline in pharmaceutical analysis
- Quality Topics of ICH Guidelines;
- Planning & Managing a Validation Program including Change Control,Scale-Up and Post-Approval Changes (SUPAC), Pre Approval Inspections (PAI) & Technology Transfer Issues

Reference Books:

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up‖, Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.